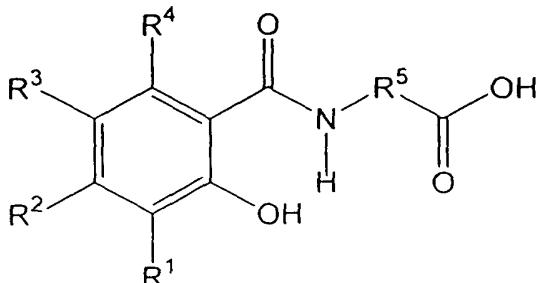


What is claimed is:

1. A disodium salt of a delivery agent having the formula



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wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

2. The disodium salt of claim 1, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

3. The disodium salt of claim 1, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

25 4. The disodium salt of claim 1, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

5. An ethanol solvate of the disodium salt of claim 1.

30 6. The ethanol solvate of claim 5, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

7. The ethanol solvate of claim 5, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

8. The ethanol solvate of claim 5, wherein the delivery agent is sodium 5 *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

9. A monohydrate of the disodium salt of claim 1.

10. The monohydrate of claim 9, wherein the delivery agent is *N*-(5-10 chlorosalicyloyl)-8-aminocaprylic acid.

11. The monohydrate of claim 9, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

15 12. The monohydrate of claim 9, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

13. A composition comprising at least about 50% by weight of the disodium salt of claim 1, based upon 100% total weight of delivery agent and salts thereof in 20 the composition.

14. The composition of claim 13, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

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15. A composition comprising:

(a) the disodium salt of claim 1, ethanol solvate thereof, or monohydrate thereof; and

(b) at least one active agent.

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16. The composition of claim 15, wherein the composition comprises at least about 50% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

5 17. The composition of claim 16, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

10 18. The composition of claim 15, wherein the composition comprises at least about 90% by weight of the monohydrate, based upon 100% total weight of hydrate of the disodium salt of the delivery agent in the composition.

15 19. The composition of claim 15, wherein the active agent is selected from the group consisting of growth hormones; human growth hormones; recombinant human growth hormones; bovine growth hormones; porcine growth hormones; growth hormone-releasing hormones; interferons;  $\alpha$ -interferon;  $\beta$ -interferon;  $\gamma$ -interferon; interleukin-1; interleukin-2; insulin; porcine insulin; bovine insulin; human insulin; human recombinant insulin; insulin-like growth factor; IGF-1; heparin; unfractionated heparin; heparinoids; dermatans; chondroitins; low molecular weight heparin; very low molecular weight heparin; 20 ultra low molecular weight heparin; calcitonin; salmon calcitonin; eel calcitonin; human calcitonin; porcine calcitonin; erythropoietin; atrial natriuretic factor; antigens; monoclonal antibodies; somatostatin; protease inhibitors; adrenocorticotropin; gonadotropin releasing hormone; oxytocin; leutinizing-hormone-releasing-hormone; follicle stimulating hormone; glucocerebrosidase; thrombopoietin; filgrastim; prostaglandins; cyclosporin; vasopressin; 25 cromolyn sodium; sodium chromoglycate; disodium chromoglycate; vancomycin; desferrioxamine; parathyroid hormone; fragments of parathyroid hormone; antimicrobials; anti-fungal agents; vitamins; analogs, fragments, mimetics and polyethylene glycol-modified derivatives of these compounds; and any combination thereof.

30 20. The composition of claim 15, wherein the active agent is selected from the group consisting of heparin and calcitonin.

21. A dosage unit form comprising:

- (a) the composition of claim 15; and
- (b) (i) an excipient,
- 5 (ii) a diluent,
- (iii) a disintegrant,
- (iv) a lubricant,
- (v) a plasticizer,
- (vi) a colorant,
- (vii) a dosing vehicle, or
- 10 (viii) any combination thereof.

22. A solid dosage unit form comprising a lyophilized mixture comprising

- (a) the disodium salt of claim 1; and
- (b) at least one active agent.

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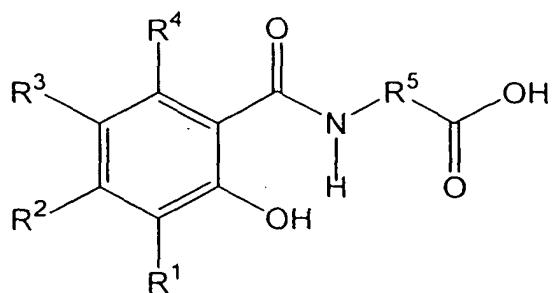
23. A method for administering heparin to an animal in need thereof, the method comprising administering orally to the animal the composition of claim 15.

24. A method for preparing a composition comprising mixing:

- 20 (a) at least one member selected from the group consisting of the disodium salt of claim 1, ethanol solvates thereof, and monohydrates thereof;
- (b) at least one active agent; and
- (c) optionally, a dosing vehicle.

25. A method for preparing an anhydrous disodium salt of a delivery agent comprising drying the ethanol solvate of the disodium salt of the delivery agent, wherein the delivery agent has the formula

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wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

R<sup>5</sup> is a substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkylene, substituted or unsubstituted C<sub>2</sub>-C<sub>16</sub> alkenylene, substituted or unsubstituted C<sub>1</sub>-C<sub>12</sub> alkyl(arylene), or substituted or unsubstituted aryl(C<sub>1</sub>-C<sub>12</sub> alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

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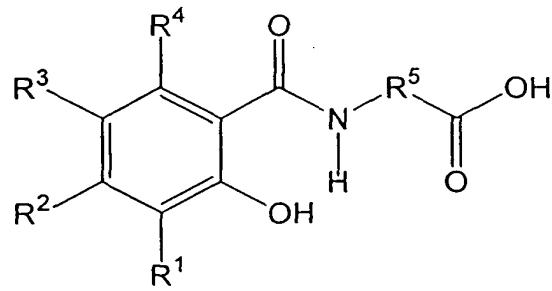
26. A method of preparing an ethanol solvate of the disodium salt of a delivery agent comprising:

(a) dissolving the delivery agent in ethanol to form a delivery agent/ethanol solution; and

20 (b) reacting the delivery agent/ethanol solution with a molar excess of a sodium containing salt to form the ethanol solvate,

wherein the delivery agent has the formula

25



30 wherein

R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

$R^5$  is a substituted or unsubstituted  $C_2$ - $C_{16}$  alkylene, substituted or unsubstituted  $C_2$ - $C_{16}$  alkenylene, substituted or unsubstituted  $C_1$ - $C_{12}$  alkyl(arylene), or substituted or unsubstituted aryl( $C_1$ - $C_{12}$  alkylene); and

R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.

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27. The method of claim 26, further comprising the step of:

(c) recovering the ethanol solvate from the solution containing the ethanol solvate formed in step (b).

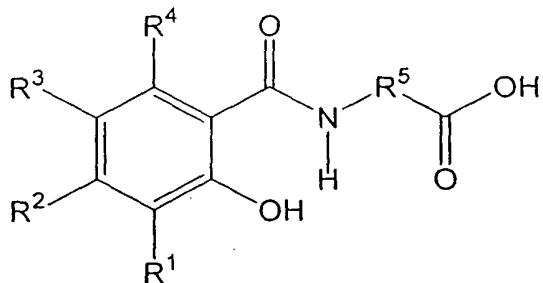
10 28. A method of preparing a monohydrate of a disodium salt of a delivery agent, the method comprising

(a) obtaining an ethanol solvate of the disodium salt of the delivery agent;

(b) drying the solvate to form an anhydrous disodium salt; and

15 (c) hydrating the anhydrous disodium salt to form the hydrate, wherein the delivery agent has the formula

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wherein

25 R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are independently hydrogen, -OH, -NR<sup>6</sup>R<sup>7</sup>, halogen, C<sub>1</sub>-C<sub>4</sub> alkyl, or C<sub>1</sub>-C<sub>4</sub> alkoxy;

$R^5$  is a substituted or unsubstituted  $C_2$ - $C_{16}$  alkylene, substituted or unsubstituted  $C_2$ - $C_{16}$  alkenylene, substituted or unsubstituted  $C_1$ - $C_{12}$  alkyl(arylene), or substituted or unsubstituted aryl( $C_1$ - $C_{12}$  alkylene); and

30 R<sup>6</sup> and R<sup>7</sup> are independently hydrogen, oxygen, or C<sub>1</sub>-C<sub>4</sub> alkyl.